

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

KATHLEEN A. ARTHUR,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 4:14-CV-52 (CEJ)
	)	
MEDTRONIC, INC. et al.,	)	
	)	
Defendants.	)	

**MEMORANDUM AND ORDER**

This matter is before the court on defendants' motion to dismiss plaintiff's first amended complaint pursuant to Fed.R.Civ.P. 9(b) and 12(b)(6). Plaintiff has filed a response in opposition and the issues are fully briefed.

**I. Background**

On December 1, 2008, plaintiff Kathleen Arthur underwent an anterior cervical discectomy and fusion surgery (ACDF) in which her surgeon implanted the Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device ("Infuse"), manufactured by defendants Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc., (collectively, "Medtronic"). Plaintiff alleges the surgery did not resolve her cervical pain and that she later developed numbness in her arm and fingers. Despite pain management treatment and additional surgical procedures, she continues to experience severe pain and numbness. Plaintiff alleges that Medtronic knew before 2008 that the Infuse device causes excessive bone growth that compresses nerves around the spinal cord and causes severe pain. She further alleges that Medtronic promoted off-label use of Infuse in the cervical region.

Plaintiff filed this action bringing multiple state law claims. Previously, the court found that the Medical Device Act (MDA), 21 U.S.C. §§ 301 *et seq.*, preempted plaintiff's claims for strict liability, failure to warn, negligence, negligent misrepresentation, and breach of implied warranty. The court also found that plaintiff's claims for fraudulent misrepresentation and breach of express warranty were not preempted, but they were not adequately pleaded. Plaintiff filed an amended complaint reasserting her fraud and express-warranty claims. Defendants assert that she has failed to cure the defects in her initial complaint and move for dismissal.

## **II. Legal Standards**

### **A. Rule 12(b)(6)**

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint. Fed. R. Civ. P. 12(b)(6). The factual allegations of a complaint are assumed true and construed in favor of the plaintiff, "even if it strikes a savvy judge that actual proof of those facts is improbable." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 (2007) (citing Swierkiewicz v. Sorema N.A., 534 U.S. 506, 508 n.1 (2002)); Neitzke v. Williams, 490 U.S. 319, 327 (1989) ("Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations."); Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) (stating that a well-pleaded complaint may proceed even if it appears "that a recovery is very remote and unlikely"). The issue is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to present evidence in support of his claim. Scheuer, 416 U.S. at 236. A viable complaint must include "enough facts to state a claim to relief that is plausible on its face." Twombly, 550

U.S. at 570; see id. at 563 (stating that the “no set of facts” language in Conley v. Gibson, 355 U.S. 41, 45–46 (1957), “has earned its retirement”); see also Ashcroft v. Iqbal, 556 U.S. 662, 678–84 (2009) (holding that the pleading standard set forth in Twombly applies to all civil actions). “Factual allegations must be enough to raise a right to relief above the speculative level.” Twombly, 550 U.S. at 555.

## **B. Rule 9(b)**

Plaintiff’s fraudulent misrepresentation claim is subject to Rule 9(b), which provides that, “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting the fraud or mistake.”

Rule 9(b)’s particularity requirement demands a higher degree of notice than that required for other claims, and is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations. To satisfy the particularity requirement of Rule 9(b), the complaint must plead such facts as the time, place, and content of defendant’s false representations, as well as the details of the defendant’s fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result. Put another way, the complaint must identify the “who, what, where, when and how” of the alleged fraud.

United States ex rel. Joshi v. St. Luke’s Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006) (internal citations omitted). A plaintiff must state an underlying basis for its assertions sufficient to provide an indicia of reliability. Id. at 557 (citation omitted). While a plaintiff need not allege specific details of every alleged fraud, the plaintiff must provide some representative examples of the alleged misconduct. Id.

## **III. Discussion**

### **A. Fraudulent Misrepresentation**

In order to state a claim for fraudulent misrepresentation under Missouri law, plaintiff must plead: (1) a representation; (2) its falsity; (3) its materiality; (4) the speaker’s knowledge of its falsity or ignorance of its truth; (5) the speaker’s intent

that it should be acted on by the person in the manner reasonably contemplated; (6) the hearer's ignorance of the falsity of the representation; (7) the hearer's reliance on the representation being true; (8) the hearer's right to rely thereon; and (9) the hearer's consequent and proximately caused injury. A plaintiff's failure to establish any one of the essential elements of fraud is fatal to recovery. Renaissance Leasing, LLC v. Vermeer Mfg. Co., 322 S.W.3d 112, 131-32 (Mo. 2010).

Plaintiff alleges that in November 2008 defendants' sales representatives told her surgeon that although Infuse was not approved for use in ACDF procedures, "it would be approved for such use by the end of 2008 or the first part of 2009." First Am. Comp. ¶17 [Doc. #38]. After the surgeon expressed concerns about using Infuse in a manner that had not been approved, the sales representatives assured him that Infuse was appropriate for use in the ACDF procedure "as Infuse would be approved in a matter of weeks" for such use. ¶18. She further alleges, on information and belief, that the sales representatives knew that her surgeon intended to use Infuse with a biomechanical cage, that this combination required premarket approval by the FDA, and that approval had not been granted and was not imminent. ¶19. She alleges that the sales representatives told her surgeon that it was appropriate to use Infuse in combination with a biomechanical cage, even though the FDA had not approved this use and approval was not imminent. ¶20.

The alleged misrepresentations regarding future approval by the FDA cannot support a fraud claim. To establish fraud under Missouri law, plaintiff must show that defendants made a misrepresentation concerning a past or existing fact. Sindecuse v. Katsaros, 541 F.3d 801, 803 (8th Cir. 2008) (citing Trotter's Corp. v.

Ringleader Rests., 929 S.W.2d 935, 940 (Mo. Ct. App. 1996)). A plaintiff cannot predicate a fraud action on a statement regarding what independent third parties will do in the future. Id. (citing Eureka Pipe, Inc. v. Cretcher–Lynch & Co., 754 S.W.2d 897, 899 (Mo. Ct. App. 1988)). “Because a statement about the future actions of third parties is really a prediction rather than a promise, this rule is just a corollary of another Missouri rule that predictions for the future are not actionable as fraudulent misrepresentations.” Id.

Similarly, plaintiff’s allegations that the sales representatives stated that it was “appropriate” to use Infuse for plaintiff’s surgery are insufficient to state a fraud claim under Missouri law. Whether a particular medical device or procedure is appropriate for a specific patient is partially dependent upon the patient’s medical history and condition, factors that are not within the purview of a sales representative’s expertise. Under this circumstance, such a statement by a sales representative amounts to no more than an expression of opinion. See Reis v. Peabody Coal Co., 997 S.W.2d 49, 65 (Mo. Ct. App. 1999) (citation omitted) (“The generally recognized distinction between statements of fact and opinion is that whatever is susceptible of exact knowledge is a matter of fact, while that not susceptible is generally regarded as an expression of opinion.”). “[M]ere statements of opinion, expectations and predictions for the future” cannot support a fraud claim. Stevens v. Markirk Constr., Inc., 454 S.W.3d 875, 881 (Mo. 2015) (quoting Lowther v. Hays, 225 S.W.2d 708, 714 (Mo. 1950)).

Plaintiff also cannot establish that her surgeon reasonably relied on statements made by sales representatives regarding whether it was “appropriate” to use Infuse in the ACDF procedure. See Hall v. Horn Med., L.L.C., No. CIV.A. 11-

1032, 2012 WL 1752546, at \*3 (E.D. La. May 16, 2012) (as a matter of law, “it is patently unreasonable for [a surgeon] to rely on a sales representative’s opinion about the type of procedure that should be employed in operating on a patient’s spine.”); cf. Uribe v. Sofamor, S.N.C., No. 8:95CV464, 1999 WL 1129703, at \*6 (D. Neb. Aug. 16, 1999) (“Off-label use of a medical device is a matter of medical judgment.”)

In addition to failing to state a claim under Missouri law, plaintiff’s allegations do not satisfy Rule 9(b)’s requirement that the circumstances constituting fraud be pled with particularity. The particularity requirement serves important purposes:

First, it deters the use of complaints as a pretext for fishing expeditions of unknown wrongs designed to compel *in terrorem* settlements. Second, it protects against damage to professional reputations resulting from allegations of moral turpitude. Third, it ensures that a defendant is given sufficient notice of the allegations against him to permit the preparation of an effective defense.

Streambend Properties II, LLC v. Ivy Tower Minneapolis, LLC, 781 F.3d 1003, 1010 (8th Cir. 2015) (citation omitted). To meet the particularity requirement, a complaint subject to Rule 9(b) “must identify who, what, where, when, and how.” Id. at 1013 (citation omitted). It must “specify[ ] the time, place, and content of the defendant’s false representations, as well as the details of the defendant’s fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result.” Id. (alteration in original). Other plaintiffs claiming that they were harmed by defendants’ off-label promotion of Infuse have satisfied these requirements. See Wright v. Medtronic, Inc., No. 1:13-CV-716, 2015 WL 328596, at \*13 (W.D. Mich. Jan. 23, 2015) (plaintiff alleged “who” the Medtronic-sponsored authors were); Hawkins v. Medtronic, Inc., 62 F. Supp. 3d 1144, 1159 (E.D. Cal.

2014) (plaintiffs satisfied rule 9 by alleging who the Medtronic-sponsored authors were, when the articles were published, the content of the allegedly false articles promoting off-label procedures, and why that content was false); Houston v. Medtronic, Inc., No. 2:13-CV-01679-SVW, 2014 WL 1364455, at \*9 (C.D. Cal. Apr. 2, 2014) (plaintiff alleged her surgeon attended conferences and read articles by named consultants); Eidson v. Medtronic, Inc., 981 F. Supp. 2d 868, 886 (N.D. Cal. 2013) (complaint identifies “Opinion Leaders” by name, describes their role in promoting off-label uses of Infuse and concealing the safety risks, and summarizes the financial gifts they received from Medtronic in exchange). By contrast with the cited cases, plaintiff’s allegations here simply do not provide the level of detail necessary to allow defendants to prepare an effective defense. Plaintiff’s fraud claim will be dismissed.

## **B. Breach of Express Warranty**

Plaintiff’s warranty claim rests on the same allegations she makes in support of her fraud claim. First Am. Comp. ¶¶38-41. Defendants argue that these allegations are insufficient to state a claim for breach of warranty.<sup>1</sup>

Under Missouri law, express warranties by the seller are created in relevant part as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

---

<sup>1</sup>Defendants also reassert their contention that plaintiff’s express warranty claim is impliedly pre-empted by the MDA. The court declines to reconsider its prior decision on this issue.

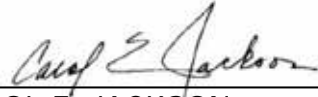
Gannon Joint Venture Ltd. P'ship v. Masonite Corp., No. 4:07CV1242 JCH, 2008 WL 2074107, at \*2 (E.D. Mo. May 14, 2008) (quoting Mo.Rev.Stat. § 400.2-313(1)(a),(b)). To state a claim for breach of an express warranty, a plaintiff must plead: (a) there was a sale of goods; (b) the seller made a statement of fact about the kind or quality of those goods; (c) the statement of fact was a material factor inducing the buyer to purchase the goods; (d) the goods did not conform to that statement of fact; (e) the nonconformity injured the buyer; and (f) the buyer notified the seller of the nonconformity in a timely fashion. Stefl v. Medtronic, Inc., 916 S.W.2d 879, 882-83 (Mo. Ct. App. 1996).

Just as with her fraud claim, plaintiff's warranty claim rests on the allegations that defendants' sales representatives told her surgeon that it was appropriate to use Infuse for her surgery, even though it had not been approved for such uses. And, as with her fraud claim, these statements amount to no more than opinion. "[M]ere expressions of opinion, belief, judgment or estimate by a dealer in sales talk" are not capable of determination and thus are not warranties. Chase Resorts, Inc. v. Johns-Manville Corp., 476 F. Supp. 633, 638 (E.D. Mo. 1979) (quoting Young & Cooper, Inc. v. Vestring, 214 Kan. 311, 521 P.2d 281, 290 (1974)). An affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty. Gen. Elec. Capital Corp. v. Rauch, 970 S.W.2d 348, 353 (Mo. Ct. App. 1998) (citation omitted). Indeed, "a seller may exaggerate the quality or value of goods without becoming liable under a theory of breach of express warranty." Id. Finally, plaintiff cannot base a warranty claim on alleged predictions regarding action by the FDA.

For the foregoing reasons,



**IT IS HEREBY ORDERED** that defendants' motion to dismiss plaintiff's first amended complaint pursuant to Fed.R.Civ.P. 9(b) and 12(b)(6) [Doc. #39] is **granted**.

A handwritten signature in black ink, appearing to read "Carol E. Jackson", is written over a horizontal line.

CAROL E. JACKSON  
UNITED STATES DISTRICT JUDGE

Dated this 24th day of August, 2015.